

**REMARKS**

In the specification, the legend of Figure 2 beginning on page 12 and the legend of Figure 3 beginning on page 14 have been amended to comply with the Examiner's directive concerning trademarks.

Claims 1 to 4 and 14 are pending. Claims 5 through 13 are canceled. Claims 1 and 14 are amended in accordance with the Examiner's instructions on pages 9, and 13-14 of the Office Action mailed March 17, 2008. Applicant reserves the right to pursue the canceled claims and the subject matter of the original claims in a continuation application.

Support for the amendment to claim 1 may be found, for example, in Examples 3-5 beginning at page 28 of U.S. appln. serial no. 07/744,649, which is incorporated in the above-captioned application by reference at page 17. Further support may be found in Examples 1 and 2 of U.S. appln. serial no. 07/744,649.

Support for the amendment to claim 14 may be found, for example, in Example 5B beginning at page 34 of U.S. appln. serial no. 07/744,649. Further support may be found in Examples 1-5 of U.S. appln. serial no. 07/744,649.

**Priority Benefit under 35 U.S.C. § 120**

The Examiner asserts that the effective filing date of the above-captioned application is its filing date, namely May 15, 2001. The Applicant respectfully disagrees and respectfully submits the effective filing date of the above-captioned application is August 8, 1991, which is the date upon which the parent application (U.S. appln. ser. no. 07/744,649) was filed. The Applicant expressly amended the specification to reflect the August 8, 1991 priority date in the Amendment and Response filed in the above-captioned application on August 15, 2005. The Amendment and Response of August 15, 2005 was entered by the Office as per the final Office Action mailed February 13, 2006. As such, the Applicant respectfully requests acknowledgment of their priority date of August 8, 1991.

The Examiner has stated that "claims 1-4 and 14 do not properly benefit under 120 by the earlier filing dates of the priority documents claimed, since those claims are rejected under 35 U.S.C. § 112, first paragraph, as lacking adequate written description and a sufficiently enabling disclosure." March 17, 2008 Office Action at p. 3. Applicants have amended claims 1 and 14 based on the Examiner's acknowledgement at page 13 of the March 17, 2008 Office Action that

the subject matter of the claims, if amended based on the Examiner's instructions, are both described and enabled under 35 U.S.C. § 112, first paragraph.

The Examiner has stated that support for the subject matter of the claims (if amended based on the Examiner's instructions) may be found in Examples 1-5B of U.S. appln. ser. no. 07/744,649. U.S. appln. ser. no. 07/744,649 is the August 8, 1991 priority document of the above-captioned application. Since, as acknowledged by the Examiner and further discussed below, both written description and enablement of the amended claims may be found in the priority document, Applicants respectfully submit the amended claims are fully described and supported under 35 U.S.C. § 112, paragraph 1 as of the priority date of August 8, 1991. Applicants, therefore, respectfully request the Examiner acknowledge the priority date of the amended claims as August 8, 1991.

#### **Illegible Oath/Declaration**

The Examiner asserts that the Oath/Declaration filed with the above-captioned application is insufficient because the oath or declaration must identify the above-captioned application by application number and filing date. The Examiner further asserts that the date of the signature of the inventor is not legible. Applicants respectfully submit that the Examiner is not looking at the latest Oath/Declaration filed in the above-captioned application. On August 15, 2005, Applicant submitted a new declaration. That declaration identifies the application number and filing date and the signature date is clear. As such, the Applicant respectfully requests the Examiner consider the August 15, 2005 declaration as filed and withdraw the objection to the Oath/Declaration.

#### **Trademark Designations**

The Examiner objects to the specification for improperly demarcated trademarks. The Applicant has amended the legend of Figures 2 and 3 in compliance with the Examiner's directives concerning trademarks.

#### **Rejections of Claims for Written Description and Enablement**

The Examiner has rejected claims 1-4 and 14 based on written description and enablement under 35 U.S.C. § 112, first paragraph. The Examiner, nevertheless, asserts that the specification would provide "an adequate written description of the products produced by the process that are clearly and particularly described in [the above-captioned] application . . . ."

March 17, 2008 Office Action at p. 9. The Examiner further asserts that the subject matter of the claims 1-4 is enabled for “that substance that is produced by the process described in Examples 3-5 . . . of the specification of Application No. 07/744,649 . . . characterized as having a molecular weight of approximately 10,000 Daltons and the amino acid composition set forth at page 11 of [the] application . . . .” March 17, 2008 Office Action at p.13. The Examiner likewise asserts that claim 14 is enabled for “that substance that is produced by the process described in Example 5B . . . of the specification of Application No. 07/744,649 . . . characterized as having a molecular weight of approximately 10,000 Daltons and the amino acid composition set forth at page 36 of Application No. 07/744,649.” *Id.*

In view of the Examiner’s statements and the Applicant’s desire to expedite the examination process, the Applicant has amended independent claims 1 and 14 to be directed, respectively, to the products of the process described in Examples 3-5 and 5B. The Applicant has additionally amended claims 1 and 14 to be directed to the methods of using a polypeptide of approximately 10,000 Daltons having the approximate respective amino acid compositions set forth, respectively, on pages 11 and 36 of U.S. appln. ser. no. 07/744,649.

Because the Applicant has complied with the Examiner’s directives concerning the written description and enablement of the subject matter of the amended claims, the Applicant respectfully requests withdrawal of the rejections of claims 1-4 and 14 for lack of written description and enablement.

#### **Obviousness Rejection of Claims 1-4**

The Examiner rejects claims 1-4 as obvious “over Bogoch *et al.* (1984) (of record; cited by Applicant as Reference #6) and Bogoch *et al.* (*Prog. Clin. Biol. Res.* 1980; 39: 407-424) (of record; cited by Applicant).” The Applicant notes that the Bogoch *et al.* (1984) reference cited as Reference #6 in the IDS filed on May 15, 2001 should be Bogoch *et al.*, Protides of Biological Fluids 31,739-747 (1984), and Reference #4 cited in the IDS should be Bogoch *et al.*, *Prog. Clin. Biol. Res.* 1980; 39: 407-424.

The Examiner asserts Bogoch *et al.* (1980) suggest that administering malignin to a subject will “be clinically effective against cancer.” March 17, 2008 Office Action at p. 17. The Examiner further asserts that “[o]ne of ordinary skill in the art at the time [of] the invention would have had a reasonable expectation of successfully treating glioma by [administering

malignin to a subject] because Bogoch *et al.* (1980) teaches [that] the survival rate of cancer patients with low levels of serum anti-malignin antibody is poorer, as compared to cancer patients with relatively high levels of serum anti-malignin antibody, the antibody that preferentially binds to glioma cells *in vivo*, and . . . is cytotoxic to glioma cells.” March 17, 2008 Office Action at p. 17.

The Applicant respectfully disagrees with the Examiner’s assertions. As acknowledged by the Examiner, Bogoch *et al.* (1980) simply suggests a use for anti-malignin antibodies. There is no expectation of success in a simple suggestion. Further, as acknowledged by the Office earlier in the examination of the above-captioned application and as established in the specification, a correlation between survival and serum anti-malignin concentration (simply in view of binding and cytotoxicity data) is insufficient to provide one of ordinary skill in the art with an expectation of success in cancer therapies. *See, e.g.*, August 15, 2005 Office Action at p. 11.

Instead, the specification teaches that the combination of data presented in the specification (along with enabling instructions for use of the malignin of the claims) provides one of ordinary skill in the art a reasonable expectation of success for practicing claims 1-4 and 14. The specification does not suggest, however, that the correlation of survival rate with higher levels of serum anti-malignin antibody, by itself or simply in combination with binding and/or cytotoxicity data, provides one of skill in the art with an expectation of success. Instead, the specification teaches that one of ordinary skill in the art would expect success in the practice of the claimed invention because, among other things, anti-malignin antibody was found (1) to be present in non-saturating amounts on cancer cells removed at surgery or autopsy, (2) to be cytotoxic to malignant glioma cells, (3) to inhibit growth of small cell lung carcinoma cells at picograms of antibody per cell, a level present when cancer cells are stained with anti-malignin antibody, (4) to bind in rat brains to glioma tissue, (5) to be bound in human glioma tissues, (6) to increase in levels in human serum with age as cancer rates rise, (7) to increase markedly when breast cancer is diagnosed, (8) to return to normal levels after successful removal of cancer tissue from patients, and, among other things, and (9) to correlate with survival when found in higher concentrations in cancer patients. *See* Application at p. 5, *see also* pages 3 and 6. As such, all of the data of the application provides the ordinary skilled artisan with an expectation of success.

The Applicant respectfully submits that a suggestion about the efficacy of a cancer therapy does not rise to the level of a reasonable expectation of success based solely on data such as a correlation between the survival rate of cancer patients and higher levels of serum antibody. Instead, the ordinary skilled artisan's reasonable expectation of success would be based on a range of confirmatory data. In the present application, and in the priority applications, the Applicant has provided a broad range of data, as discussed above, that provides the ordinary skilled artisan with a reasonable expectation of success.

In fact, the Office argued in previous examination of this very application that an expectation of success cannot be based simply on the correlation data provided in the application in view of cytotoxicity and binding. In the Office Action mailed February 15, 2005 in the above-captioned application, the Office wrote: "[T]he fact that a higher level of anti-Recognin is associated with longer survival of cancer patients would not lead a skilled artisan to conclude that anti-Recognin causes longer survival. Therefore, a person of ordinary skill in the art would not expect that artificially increasing the level of anti-Recognin would have the effect of increasing a patient's survival time." February 15, 2005 Office Action at p. 12 (emphasis added). Thus, the Office previously argued that the ordinary skilled artisan would NOT have a reasonable expectation of success based on the correlation data of Bogoch *et al.* (1984). The Office's earlier argument directly contradicts the Office's present assertion that the teachings of Bogoch *et al.* (1984) and Bogoch *et al.* (1980) would render claims 1-4 obvious.

The Applicant respectfully agrees with the Office's statement of February 15, 2005. The discussed correlation alone does not provide the ordinary skilled artisan with a reasonable expectation of success.

Since the Office has already asserted that the ordinary skilled artisan does not have a reasonable expectation of success from a correlation between survival rate and serum antibody concentration, the Applicant respectfully submits that the current rejection of claims 1-4 as obvious over Bogoch *et al.* (1980) and Bogoch *et al.* (1984) should be withdrawn as contrary to earlier assertions of the Office.

#### **Obviousness Type Double Patenting Rejection of Claims 1-4**

The Examiner rejects claim 1 for non-statutory obviousness-type double patenting over claims 1-16, 20, 22, and 24-26 of U.S. Patent No. 5,866,690. The Examiner asserts that

“although the invention is now intended for use in inhibiting glioma cells expressing malignin in a subject, the claims do not recite a limitation requiring that the subject have a glioma [and] in as much as the subject need not have a glioma, it is submitted that the process that would have been obvious to one of ordinary skill in the art at the time of the invention was made in light of claims 1-6, 20, 22, and 24-26 of U.S. Patent No. 5,866,690 is a process that is materially and manipulatively indistinguishable from the active process of the claimed invention.” March 17, 2008 Office Action at p. 20.

In view of the Examiner’s rejection, the Applicant has amended claim 1 to be directed to a subject “suffering from glioma.” As such, the Applicant respectfully requests the Examiner withdraw the rejection of claim 1 for non-statutory obviousness-type double patenting.

The Examiner further rejects claims 2-4 for non-statutory obviousness double patenting in view of the rejection of claim 1. The Applicant respectfully submits the amendment to claim 1 obviates the rejection of claims 2-4 and requests the rejection be withdrawn.

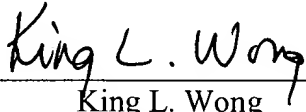
**CONCLUSION**

It is believed that the present claims are in condition for allowance and Applicant earnestly requests the same. An early and favorable action on the merits is earnestly solicited.

The Examiner is invited to contact the undersigned attorney to expedite allowance. The Commissioner is authorized to charged any fees or overpayments associated with this application to Kenyon & Kenyon LLP **Deposit Account No. 11-0600.**

Respectfully submitted,

KENYON & KENYON LLP

  
\_\_\_\_\_  
King L. Wong  
Reg. No. 37,500

Dated: July 14, 2008

1500 K Street, N.W.  
Washington, DC 20005  
Telephone: 202/220-4200  
Facsimile: 202/220-4201  
Customer No. 23838